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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/767,476 | 01/28/2004 | John R. Stuelpnagel | 01-00008 | 5069 |
| 29389 | 7590 | 09/13/2006 | EXAMINER | |
| ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975 | | | STEELE, AMBER D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1639 | |

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/767,476 | Applicant(s) STUELPNAGEL ET AL. | |
| | Examiner Amber D. Steele | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7 attached</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-28 were canceled and new claims 29-50 were added in the preliminary amendment received on January 28, 2004.

Information Disclosure Statement

2. The information disclosure statement filed March 16, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but all of the information referred to therein has not been considered.

Specification

3. The disclosure is objected to because of the following informalities: The description of the figures states that Figures 1A, 1B, 1C, 1D and 1E depict several different two component systems. However, the description of the drawings should state that Figures 1A, 1B, 1C, 1D, 1E, and 1F depict several different two component systems.

Appropriate correction is required.

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 29-32, 35-39, 41-42, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Rava et al. U.S. Patent 5,545,531 issued August 13, 1996.

For present claims 29 and 41, Rava et al. teach "array or arrays" including individual DNA or probe (e.g. bioactive) chips in each well of a microplate wherein the "first substrate" is a microtiter plate and the "second substrate" is a wafer or discretely placed probes and each probe is different (please refer to abstract; Figures 3, 4, 5, 6, 7; columns 1-12; claims 1-4).

For present claim 30, Rava et al. teach hybridization of probes to targets within the microtiter plate and/or chips (please refer to columns 3, 7).

For present claim 31, Rava et al. teach microtiter plates (please refer to Figures 3, 4, 5, 6, 7; columns 2, 4, 8, 9-10).

For present claims 32 and 42, Rava et al. teach 96-well microtiter plates (please refer to Figures 3, 4; columns 2, 4, 8, 9-10).

For present claims 35 and 45, Rava et al. teach the biological reagents or probes are DNA, RNA, nucleic acid, agonists and antagonists for cell membrane receptors, toxins, bivenoms, viral epitopes, hormones, peptides, steroids, receptors, enzymes, substrates, cofactors,

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drugs, lectins, sugars, oligos, oligosaccharides, proteins, or antibodies (please refer to columns 2-3, 7, 11, 12; claims 1-4).

For present claims 36-38 and 46-48, Rava et al. teach 10, 100, 1000, 2500, 10,000 (also in 1 cm^2), 48,400, 50,000, 100,000, 1,000,000, 4,800,000, or 10,000,000 probes per well of a 96-well microtiter plate wherein the diameter of an individual well of a 96-well microtiter plate is less than 1 square centimeter or approximately 0.25 mm^2 (e.g. about 10,000,000 or less; please refer to columns 2, 9-10; Figure 4).

For present claims 39 and 49, Rava et al. teach that the biological reagents can be directly attached to the wafer or substrate wherein the biological reagent or substrate provides an adequate surface for attachment (please refer to columns 9-10).

Therefore, the teachings of Rava et al. anticipate the presently claimed invention.

7. Claims 29-32, 35-42, and 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes U.S. Patent 5,549,974 issued August 27, 1996.

For present claims 29 and 41, Holmes teaches chemical (e.g. bioactive) arrays with a “first substrate” which can be wells or a microtiter plate and a “second substrate” which can be beads, resins, pins, etc. in the wells of a microtiter plate with different chemicals on each bead, resin, pin, etc. (please refer to columns 8-9, 11-30).

For present claim 30, Holmes teaches binding and hybridization to chemicals in the array or wells (please refer to columns 22, 29-30).

For present claim 31, Holmes teaches wells and microtiter plates (please refer to column 9, 24, 27).

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For present claims 32 and 42, Holmes teaches 96-well microtiter plates (please refer to column 27).

For present claims 35 and 45, Holmes teaches "peptide structural analogs" or thiazolidinones, metathiazanone, or peptidomimetics (please refer to abstract; columns 2-4, 8).

For present claims 36-38 and 46-48, Holmes teaches beads from 1nm to 100 μ m with capacities for 100 to 500 pmol of molecules per bead with about 100,000 beads per pool (e.g. about 10,000,000 or less agents per square centimeter; please refer to columns 9, 11, 30).

For present claims 39 and 49, Holmes teaches that the chemicals are coupled to the array locations either with linkers, directly, or wherein the bead or pin is modified to accept the chemicals (please refer to columns 11-12, 25, 27).

For present claims 40 and 50, Holmes teaches beads or spheres from 1nm to 100 μ m (please refer to columns 9, 11, 24-25, 30).

Therefore, the teachings of Holmes anticipate the presently claimed invention.

8. Claims 29-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Felder et al. U.S. Patent 6,458,533 filed December 22, 1998 (effective filing date of December 19, 1997).

For present claims 29 and 41, Felder et al. teach apparatuses or biological arrays comprising a surface of test regions which can be wells of a microtiter plate which are further subdivided into smaller subregions (e.g. wells within wells) with the biological reagents attached which can be different (please refer to abstract; Figures 2, 4, 5a, 5b, 5c, 9, 10, 12, 15, 16, 17, 18, 19, 20a, 20b, 22; columns 1-33; Examples 1-20).

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For present claim 30, Felder et al. teach hybridization or binding in the wells or subregions (please refer to columns 3-4, 9-32; Examples 1, 2, 4, 5, 6, 12, 13, 14, , 15, 16, 17, 18, 19, 20).

For present claim 31, Felder et al. teach microtiter plates (please refer to columns 2-3, 5-6, 10, 13; Example 1).

For present claims 32-34 and 42-44, Felder et al. teach 96, 384, and 1536 well microtiter plates (please refer to columns 2, 5-6, 10, 13; Example 1).

For present claims 35 and 45, Felder et al. teach that the biological reagents or probes are RNA, oligos, DNA, PNA, enzymes, polymers, agonists or antagonists for cell membranes, toxins, venoms, viral epitopes, hormones, steroids, peptides, receptors, lectins, sugars, nucleic acids, oligosaccharides, proteins, antibodies (please refer to column 4).

For present claims 36-38 and 46-38, Felder et al. teach regions of about 1 to 700 mm²; subdividing a 1536-well plate (e.g. each well less than 1 cm²; approximately 1.7 mm diameter) into about 4 to 900 wells wherein each well has 9-36 reagents or 32,400 reagents and 96 well plates would accommodate more samples due to the larger size (e.g. each well less than 1 cm²); and 345,000 test reagents (e.g. about 10,000,000; please refer to columns 2, 6-7).

For present claims 39 and 49, Felder et al. teach direct attachment of probes to surfaces (please refer to columns 4, 7-10).

For present claims 40 and 50, Felder et al. teach beads (please refer to column 5).

Therefor, the presently claimed invention is anticipated by the teachings of Felder et al.

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9. Claims 29-32, 35-42 and 45-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. U.S. Patent 5,922,617 filed November 12, 1997.

For present claims 29 and 41, Wang et al. teach a solid surface (e.g. first substrate) with circular grooves which are U-shaped, V-shaped, flat-bottomed, or have corrugated walls and the grooves can be separated with walls (e.g. wells) that contain microbeads or arrays (e.g. second substrate) in the grooves (please refer to Figures 2C, 2D, 3A, 3B, 4, 5, 6; columns 2-9, 13-15). In addition, Wang et al. teach 96-well plates (please refer to column 5, lines 46-59). Furthermore, Wang et al. teach organic molecules (e.g. bioactives) in the arrays (please refer to columns 3-5).

For present claim 30, Wang et al. teach hybridization (please refer to columns 4 and 9).

For present claim 31, Wang et al. teach microtiter plates (please refer to column 5).

For present claims 32 and 42, Wang et al. teach 96-well plates (please refer to column 5).

For present claims 35 and 45, Wang et al. teach that the organic molecules can be nucleic acids, RNA, receptor, ligand, antibodies, biotin, enzymes, DNA, proteins (please refer to columns 3-5).

For present claims 36-38 and 46-48, Wang et al. teach beads of 1μ - 100μ wherein more than 10^6 beads can be arrayed on less than 2×2 cm solid surface and 20 - 10^6 molecules per 1 - 200μ of solid surface (e.g. about 10,000,000 or 100,000 or 10,000 bioactives per square centimeter; please refer to columns 6-8).

For present claims 39 and 49, Wang et al. teach directly binding the component to the solid surface (please refer to column 3).

For present claims 40 and 50, Wang et al. teach microbeads (please refer to columns 5-8).

Therefore the teachings of Wang et al. anticipate the presently claimed invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 29, 31, 35, 37, 38, 40, 41, 45, 47, 48, and 50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-9, 12-18, 24, 25, 26, 27, 28, 29, 30 of U.S. Patent No. 6,429,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the claims of U.S. Patent 6,429,027 are drawn to an array comprising a microtiter plate with wells (e.g. first substrate) and microbeads (e.g. second substrate) with bioactives.

For present claims 29 and 41, U.S. Patent 6,429,027 claims a composite array (e.g. array of arrays) comprising a substrate with a plurality of assay locations with discrete sites which can

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be wells of a microtiter plate (e.g. first substrate) and a population of microspheres (e.g. a second substrate) with bioactive agents (please refer to claims 1, 3, 4, 7, 8, 9, 14).

For present claim 31, U.S. Patent 6,429,027 claims wells of a microtiter plate (please refer to claims 3, 8).

For present claims 35 and 45, U.S. Patent 6,429,027 claims the bioactive agents are nucleic acid, nucleic acid analogs, or protein (please refer to claims 12, 13, 25, 26, 27, 28, 29, 30).

For present claims 37-38 and 47-48, U.S. Patent 6,429,027 claims 1000 discrete sites per cm^2 , 1,000,000 sites/ cm^2 , and 10,000 discrete sites (please refer to claims 15-24).

For present claims 40 and 50, U.S. Patent 6,429,027 claims microspheres (please refer to claims 1, 7).

Therefore, the presently claimed invention is obvious over the claims of U.S. Patent 6,429,027.

12. Claims 29, 35, and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38, 40, 41, 42, 43, 44 of copending Application No. 09/189,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present claims and the claims of Application 09/189,543 are drawn to arrays with a first substrate comprising wells and a second substrate (e.g. microspheres) with bioactive agents.

For present claim 29, Application 09/189,543 claims a (first) substrate with discrete wells and a population of microspheres (e.g. second substrate) with bioactive agents (please refer to claim 38).

For present claim 35, Application 09/189,543 claims the bioactive agents are nucleic acids, DNA, single stranded nucleic acids, double stranded nucleic acids, or proteins (please refer to claims 40-44).

For present claim 40, Application 09/189,543 claims microspheres (please refer to claim 38).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 29 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 4, 5, 6, 7 of copending Application No. 10/363,240. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the claims of Application 10/363,240 are drawn to arrays comprising a (first) substrate with wells and a second substrate or cells with bioactives on the surface.

For present claim 29, Application 10/363,240 claims a (first) substrate with wells and a plurality of cells (e.g. second substrate with bioactives; please refer to claims 1 and 3).

For present claim 35, Application 10/363,240 claims that the cells can bind an antibody ligand or the cells comprise a binding partner, peptide, or candidate agents (please refer to claims 4-7).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 30, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 49, 50, 51, 52, 55 of copending Application No. 09/606,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in Application 09/606,369 are drawn to arrays comprising a microtiter plate with wells (e.g. first substrate) and a second array component (e.g. second substrate) with bioactive agents.

For present claims 29 and 41, Application 09/606,369 claim a first array component (e.g. first substrate) that can be a microtiter plate with wells and a second array component (e.g. second substrate) with a bioactive agent (please refer to claims 29, 30, 36, 37, 38, 39, 40, 44, 45, 49).

For present claim 30, Application 09/606,369 claim a hybridization chamber (please refer to claims 29, 36, 37, 38, 39, 40, 49, 52).

For present claim 31, Application 09/606,369 claim microtiter plates with wells (please refer to claims 30, 40, 44, 45).

For present claims 32-34 and 42-44, Application 09/606,369 claim 96-well, 384-well, and 1536-well microtiter plates (please refer to claim 45).

For present claims 35 and 45, Application 09/606,369 claim the bioactive are peptides, nucleic acids, or target analytes with fluorescent labels (please refer to claims 51, 55).

For present claims 36-38 and 46-48, Application 09/606,369 claim bioactive agents at a density of about 10,000,000 to 2,000,000,000 per cm² or about 100,000 to 10,000,000 per cm² (please refer to claims 42, 43).

For present claims 40 and 50, Application 09/606,369 claim microspheres (please refer to claims 36, 49).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS

August 25, 2006

My-Chau Tran
Patent Examiner
AU1639

